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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/551,685 | 07/11/2006 | Egon Luther | ZEI-3286/500343.20307 | 5541 |
| 26418 | 7590 | 02/16/2010 | | |
| REED SMITH, LLP ATTN: PATENT RECORDS DEPARTMENT 599 LEXINGTON AVENUE, 29TH FLOOR NEW YORK, NY 10022-7650 | | | EXAMINER LIPITZ, JEFFREY BRIAN | |
| | | | ART UNIT 3769 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/551,685 | Applicant(s) LUTHER ET AL. | |
| | Examiner JEFFREY B. LIPITZ | Art Unit 3769 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-16, 18 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-16, 18 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/4/2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 1, 2010 has been entered.

Response to Arguments

Applicant's arguments filed February 1, 2010 with regards to the 112 First Paragraph rejection have been fully considered but they are not persuasive. Although Examiner erroneously identified claim 18 instead of cancelled claim 17, claim 16, or the recitation of cancelled claim 17, it is still enigmatic as to how UV light is used to illuminate the ophthalmic tissue. How is light in the UV spectra used to observe a patient's eye without an optical element or a fluorescent substance that would enable the UV light to be converted to visible light? The paragraphs identified by Applicant do not explain how this phenomenon occurs. As an aside, if Examiner appears to have made an honest error, a call should be placed by Applicant to Examiner to clarify the matter. This approach is advantageous to expedite prosecution and is a professional courtesy that would be undertaken by Examiner if the situation were reversed. The 112 First Paragraph rejection of claim 16 has been added to this action.

Applicant's arguments/amendments with respect to the 112 Second Paragraph rejections have been fully considered and are persuasive. The 112 rejections of claims 13, 16 and 18 have been withdrawn.

Applicant's arguments with respect to the prior art rejections have been fully considered but they are not persuasive.

Applicant asserts that SUMIYA does not describe an illumination and irradiation device that generates specific patterns. However, as discussed in the interview with Applicant on November 16, 2009, Applicant provides no disclosure or definition of a pattern or a profile. Thus, Examiner has interpreted any illumination including a spot as a pattern or a profile. A point or spot profile may not be an intricate profile, but it nonetheless is a profile. Furthermore, a pattern is usually defined as a theme of reoccurring events or objects. Although one spot is not a pattern, a series of spots is a pattern. Applicant's claim recites a "means for coupling a complete of the specific illumination patterns". Applicant has assumed that this recitation limits a pattern to only include spots generated at the same time. Sumiya's invention can function at a uniform pulse rate, which "means for coupling..." would deliver the spots in a temporal pattern. Thus, Sumiya's invention can clearly generate a complete pattern or profile.

Applicant has also amended independent claim 13 to include the recitation "wherein a spectral range and spatial range of the illumination beam is influenced by the optical filters, diaphragms and or optoelectronic light modulators". Applicant argues that it will not be possible for the spatial range of a spot to be influenced by the optical filters, diaphragms and or optoelectronic light modulators. However, this is not correct. In the

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previous office action, Examiner identified “a lens (12), a pinhole (13), a beam splitter (14), a quarter waveplate (16), and a dichroic mirror (17), another lens (18), and scanning mirrors (19 and 20)” as elements that generate specific illumination profiles and or patterns. “Specifically, the pinhole (13) can be construed as a diaphragm, and the lenses can be construed as optical filters. All of the aforementioned components are capable of enabling generation of specific illumination patterns and or profiles. Many of the components are optoelectronic light modulators, since they are controlled by electronic means or driving circuit (46; Column 5, Lines 35-67).” The scanning mirrors or optoelectronic light modulators clearly influence the spatial range of the illumination beam, since they direct the beam/spots to particular points in the xy plane of the eye. The pinhole (13) like the diaphragm of Applicant also inherently influences the size of the spot. The dichroic mirror (17) and the beamsplitter (14) reflect some wavebands of light and transmit others, and thus, inherently influence the spectral range of the illumination light. Applicant amendments to claim 13 are not sufficient to change the prior art rejections. Those rejections have been maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 13-15, 21 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Sumiya (US 6,585,723 B1).

Regarding claims 13, 25, and 26, Sumiya teaches an illumination and irradiation unit, which is comprised of an observation system or optical system (30) and a corneal shape measurement optical system (10). The corneal shape measurement optical system (10) contains an illumination source (11) and a means for coupling light or a dichroic mirror (21) from the illumination source (11) into the parallel beam path of the observation system (30; Column 3, Lines 35-67; Column 4, Lines 1-17; Figure 2).

Sumiya also teaches a control unit (40) that controls illumination source (11), and the means for generating specific illumination patterns or profiles (ie...lens 18 and scanning mirrors 19 and 20). In addition, Sumiya teaches a lens 12, a pinhole 13, a beam splitter (14), a quarter waveplate (16), and a dichroic mirror (17), a lens (18), and scanning mirrors (19 and 20) that generate specific illumination profiles and patterns (Column 6, Lines 47-67). Specifically, the pinhole (13) can be construed as a diaphragm, the lenses are construed as optical filters and the scanners (19 and 20) are construed as optoelectronic light modulators. All of the aforementioned components are capable of enabling generation of specific illumination patterns and or profiles. Many of the other components are optoelectronic light modulators, since they are controlled by electronic means or driving circuit (46; Column 5, Lines 35-67). As discussed in the Response to Aguments section, supra, the beamsplitter (14) and dichroic mirror (17) reflect some wavebands of light and transmit others, and thus, inherently influence the spectral range of the illumination light. The scanning mirrors or optoelectronic light modulators clearly

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influence the spatial range of the illumination beam, since they direct the beam/spots to particular points in the xy plane of the eye. The pinhole (13) like the diaphragm of Applicant also inherently influences the size of the spot, which is interpreted as an influence over the spatial range of the spot.

The corneal shape measurement optical system (10) is arranged in a shared housing (1) with other optical systems and a control system. The corneal shape measurement optical system (10), the observation optical system (30), the laser irradiating optical system (25), the eyeball position detecting optical system (35), and the control system (40) are all used in combination with one another to perform corneal surgery (Column 3, Lines 2-25; Figures 1 and 2).

Regarding claims 14-15, Sumiya teaches a computer or monitoring unit (8) comprised of an input unit (41), a processing unit (42), a display unit (43), and an output unit (44). The processing unit (42) processes signals sent from the photodetector (23), signals sent from the corneal shape measurement optical system (10) and the inputted irradiation conditions in order to obtain ablation data. The data processed by the processing unit (42) is sent to the control system (40). Processed data may also be sent to the display unit (43). In addition to controlling the processing unit (42) and the control system (40), the computer (8) functions at least at the level of a basic computer, which can store or record ablation data or radiation dosage, irradiation patterns and positions. Sumiya specifically mentions that it has more than one interface for transferring data (a printer and a floppy disc drive; Column 3, Lines 21-24; Column 5, Lines 35-60); however, since computer (8) presumably can function as a basic computer, it would

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also contain other interfaces for transferring data such as USB ports, data DVD writer, data CD writer, a zip drive, etc.

Regarding claim 21, Sumiya teaches a dichroic mirror or beamsplitter (21) that enables the optical axis of the measurement optical system (10) and laser irradiating optical system (25) to be coaxial with the optical axis of the observation optical system (30). In addition, the dichroic mirror (21) only permits the transmission of visible light, reflecting the infrared laser beam and the exciter laser beam (Columns 3, Lines 62-67; Column 4, Lines 1-9). Thus, the dichroic mirror (21) protects the observer from unwanted radiation by filtering out the exciter and infrared laser beams.

Regarding claim 23, Sumiya teaches that there is an eyeball position detecting optical system or eyetracker unit (35) and a corneal shape measurement unit (10; Columns 4-5, Lines 61-34).

Regarding claim 24, Sumiya teaches that the observation optical system (30), which includes binocular microscope (3) and illumination unit (4), is illustrated as modular units for installation in the parallel beam path of the laser irradiating optical system (25; Figure 1). In other words, the observation optical system (30), containing the illumination unit (4) and the microscope unit (3), is attached to the main body (1) containing other subassemblies by the arm portion 2 (Column 3, Lines 3-25). Since several components of the observation optical system (3) and the corneal shape measurement optical system 10 (construed as the illuminating and irradiating unit as claimed) are shared, therefore both modular units are designed for retrofit installation, since each unit requires the other in order to properly function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sumiya (as discussed supra).

Regarding claim 18, Sumiya teaches that the illumination source emits light at about 800 nm (Column 4, Lines 1-4). However, he does NOT teach that the laser beam (11) generates illumination light around 690 nm, as claimed. However, Sumiya does teach the use of additional illumination sources (4) for providing visible light, which is approximately 380-750 nm (Column 4, Lines 37-44). Furthermore, Applicant provides no rationale for using one illumination wavelength over another. Therefore, Examiner interprets any light source as an illumination source if that light is capable of being used for illumination.

Regarding claim 22, Sumiya teaches does NOT teach that the illumination source (11) is not arranged within the illumination unit. However, making an element separate is not of innovation. It would have been an obvious matter of design choice to make the illumination source separate from the illumination unit or to make the illumination unit a modular unit for retrofit installation into an ophthalmic instrument,

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since such modifications would have involved making the parts separately or portable. Making a part separate, if it is desirable, is generally recognized as being within the level of ordinary skill in the art. In re Dulberg, 289 F.2d 522, 129 USPQ 348,349 (CCPA 1961). Furthermore, Applicant admits that positioning light sources outside of a main housing, and using a light guide or conductor to transmit the light to a main housing is common to one of ordinary skill in the art (Applicant's Arguments/Remarks: Pages 10-11).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sumiya as applied to claim 13 above, and further in view of Haisch (20040152987).

Regarding claim 16, Sumiya does not teach that the illumination source has emits a narrow band light around 365 nm, as claimed. Attention is directed to Haisch, who teaches an inspection system for observing a fluorescent marker in a tissue (Abstract). Haisch teaches using an ultraviolet illumination source to excite a fluorescent marker (Paragraph [0014]). It would have been obvious to use a UV source for illumination of tissue in instances where there is auto-fluorescence of the tissue in the UV spectrum or in instances where a fluorescent dye is added to the tissue to provide fluorescence in response to UV light. The choice of UV illumination wavelengths will depend on the excitation wavelength of the tissue or dye. Hoechst dye, for example, is excited at about 365 nm, and will result in fluorescence of cell nuclei.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY B. LIPITZ whose telephone number is (571)270-5612. The examiner can normally be reached on Monday to Thursday, 10 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on (571)272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JEFFREY B LIPITZ/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art
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